



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/603,818 | 06/26/2003 | Thomas Nilsson | 239637US0 | 2767 |

22850 7590 09/09/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

HAGHIGHATIAN, MINA

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,818

Applicant(s)

NILSSON ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 9-13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin (WO 0178737).

Gavin teaches medical combinations comprising formoterol and budesonide. The combinations are used for prophylaxis and treatment of respiratory diseases (see abstract). The active agents may be a racemate, solvate, hydrate or functional derivative thereof. The formulations may comprise other active agents such as fluticasone propionate, beclomethasone dipropionate, mometasone furoate or triamcinolone acetonide, sodium cromoglycate, nedocromil sodium, leukotriene antagonists, salbutamol, salmeterol, tiotropium, etc (see pages 5-6). The formulations may be in a form for inhalation such as fine particle dust administered via metered dose aerosols. Formulations for inhalation include powder compositions which will preferably contain lactose. The active ingredients will have a particle size of less than 100 microns, and preferably from 1 to 5 microns (see page 6).

The amounts of each active agent is disclosed in various examples, such as example 3, where a dry powder formulation comprises 24 microgram of (R,R)-formoterol fumarate and 200 microgram of budesonide, thus meeting the concentration

Art Unit: 1616

limitation of claims such as claim 7. The process of making the said formulations are disclosed in page 9.

Claims 1-7, 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Trofast (6,030,604).

Trofast teaches a dry powder composition comprising one or more potent pharmaceutically active substances and a carrier substance, all of which are in finely divided form. The active substance suitable for use in the invention include ciclesonide, formoterol, budesonide, mometasone, fluticasone, salmeterol, etc (see col. 1, lines 26-62). The particle size of the active ingredients is said to be less than 10 microns and preferably between 1 and 7 microns. The formulations comprises about 6 microgram of formoterol and 100 microgram of budesonide per unit dose (see col. 2, lines 3-10 and 15-49). The said formulations can be administered via dry powder metered dose inhalers, to patients suffering form disorders such as respiratory disorders (col. 3, lines 20-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin (WO 0178737) as applied to claims 1-4, 6-7, 9-13, 15-16 above, and further in view of Haikrainen et al (WO 0064519).

Gavin, discussed above, lacks specific disclosure on the separation of the powdered active ingredients.

Haikrainen teaches powder inhaler for combined medicament. The device comprises two or more medicament containers for different drug powders which are

Art Unit: 1616

inhaled a combined medication, and separate aerosolization channels for each drug powder (see abstract and page 3). The first and the second medicament containers are separated so that the active ingredients can not be mixed during storage. The suitable combinations of active agents include formoterol and budesonide; salmeterol and beclomethasone dipropionate; salmeterol and fluticasone, etc (see page 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have employed the device of Haikarainen et al to deliver the formulations of Gavin because the device of Haikarainen is disclosed to be advantageous for delivering powdered combination medicaments where by storing the active agents separately, the problem of aggregation is resolved.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/603,819 (20040258625). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Here claims 1-17 are generic to all that is recited in claims of copending Application No. 10/603,819 (20040258625). That is, claims of copending Application No. 10/603,819 (20040258625) fall entirely within the scope of claims 1-17. Specifically, the method of treating patients by inhalation of a combined doses of dry powder medicaments, and the compositions recited in instant claims are the same as the method of administering metered dry powder combined doses and the therapeutic metered dose inhalation of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/870,907 (20050042174). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Here claims 1-17 are generic to all that is recited in claims of copending Application No. 10/870,907 (20050042174). That is, claims of copending Application No. 10/870,907 (20050042174) fall entirely within the scope of claims 1-17. Specifically, the method of treating patients by inhalation of a

Art Unit: 1616

combined doses of dry powder medicaments, and the compositions recited in instant claims are the same as the method of administering metered dry powder combined doses and the therapeutic metered dose inhalation of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/870,909 (20050042175). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Here claims 1-17 are generic to all that is recited in claims of copending Application No. 10/870,909 (20050042175). That is, claims of copending Application No. 10/870,909 (20050042175) fall entirely within the scope of claims 1-17. Specifically, the method of treating patients by inhalation of a combined doses of dry powder medicaments, and the compositions recited in instant claims are the same as the method of administering metered dry powder combined doses and the therapeutic metered dose inhalation of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending

Art Unit: 1616

Application No. 10/703,505 (20050053553). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Here claims 1-17 are generic to all that is recited in claims of copending Application No. 10/703,505 (20050053553). That is, claims of copending Application No. 10/703,505 (20050053553) fall entirely within the scope of claims 1-17. Specifically, the method of treating patients by inhalation of a combined doses of dry powder medicaments, and the compositions recited in instant claims are the same as the method of administering metered dry powder medicaments of anticholinergics and/or other medicaments and the therapeutic metered dose inhalation of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghigatian
September 02, 2005



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER